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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,128	01/27/2006	Lan Bo Chen	00530-115US1 DFCI 739.02	8712
26161 7590 03/19/2008 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER TUNG, JOYCE	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 03/19/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,128	<b>Applicant(s)</b> CHEN ET AL.	
	<b>Examiner</b> Joyce Tung	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.                                                          | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, 19-22, and 24 drawn to an isolated nucleic acid comprising a nucleotide sequence which is at least 70% identical to the sequence of SEQ ID NO: 3, an expression vector comprising the nucleic acid sequence, and a cultured cell comprising the vector and a method for producing a polypeptide by culturing the cultured cell.

Group II, claim(s) 14-16, drawn to a nucleic acid comprising SEQ ID NO: 1 and an isolated nucleic acid comprising a sequence under low stringency or high stringency condition to hybridize to the sequence which consists of SEQ IDNO: 1.

Group III, claim(s) 17-18 drawn to an isolated peptide comprising an amino acid sequence which is at least 70% identical to the amino acid sequence of SEQ ID NO: 2.

Group IV, claim(s) 23, drawn to a purified antibody.

Group V, claim(s) 25-33, drawn to a method for detecting a cellular proliferative disorder in a subject and a method for monitoring a subject undergoing a therapeutic treatment via measuring the expression level of a gene encoding a polypeptide with a sequence of SEQ ID NO: 2 in a test sample.

Group VI, claim(s) 34, drawn to a method for targeting a cellular proliferative disorder in a subject via administering to the subject an agent that can bind to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2.

Group VII, claim(s) 35, drawn a method for expressing a foreign polypeptide in a cell in vivo in which the foreign polypeptide binds to a polypeptide with the amino acid sequence of SEQ ID No: 2.

Group VIII, claim(s) 36, drawn to a method for introducing a foreign nucleic acid into cell in vivo in which the foreign nucleic acid is complementary to SEQ ID NO: 1.

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Group IX, claim(s) 37, drawn to a method for targeting a cellular proliferative disorder in a subject via administering an agent that binds to a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 3.

Group X, claim(s) 38, drawn to a method for targeting a cellular proliferative disorder in a subject via modulating the expression level of a gene encoding to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2.

Group XI, claim(s) 39-40, drawn to a method for modulating the cellular pump mechanism of a resistant tumor cell comprising an agent that binds to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2.

Group XII, claim(s) 41-43, drawn to a method for screening for a therapeutic agent for treating a drug-resistant tumor cell by measuring the level of synthesis of the gene product of the reporter gene.

Group XIII, claim(s) 44-46, drawn to a cell for screening for a therapeutic agent for treating a drug-resistant tumor cell comprising a reporter gene.

Group XIV, claim(s) 47-48, drawn to a method of making an antibody.

Group XV, claim(s) 49, drawn to a method for modulating expression of a gene responsible for controlling cellular pump mechanisms in cell via an effect amount agent that binds to a nucleic acid comprising the sequence of SEQ ID NO: 3.

Group XVI, claim(s) 50, drawn to a method for delivering a suicide protein to a tumor cell comprising contacting a vector comprising the sequence of SEQ ID NO: 3.

It is noted that claim 13 is an improper linking claim linking independent and distinct sequences, and thus has not been included in any of the above groups.

2. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As set forth above, the product groups, Groups I-IV and Group XIV include nucleic acid sequences, polypeptides and antibody and cell. The nucleic acid sequences, the polypeptides, the antibody have different chemical structures, different properties and different functions. The cell is different from nucleic acid sequences, polypeptides and antibody because cell has its own structure and function.

As set forth above, the method groups, Groups V-XIII and XV-XVII have different and non-overlapping method steps as recited in each independent claim.

Therefore, the inventions listed as Groups I-XVII do not relate to a single general inventive concept.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/  
Primary Examiner, Art Unit 1637

Joyce Tung  
March 10, 2008